

**Statement on the
Medical Evaluation and Treatment of Persian Gulf War
Veterans Having Difficult to Diagnose or Ill Defined Conditions**

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Mr. Chairman and Members of the Subcommittee:

I welcome this opportunity to discuss VA's medical management of Persian Gulf War veterans having difficult to diagnose or ill-defined conditions.

Before commenting on the specific subject of today's hearing, I will take this opportunity to refresh your memory about VA's overall response to Gulf War veterans' healthcare needs, describing specific elements of our approach to the diagnosis and treatment, as well as research, of the illnesses of these veterans.

BACKGROUND

On August 2, 1990, Saddam Hussein invaded Kuwait, and American military personnel were deployed to Southwest Asia soon thereafter. Ultimately, nearly 700,000 U.S. troops were deployed to the Persian Gulf in Operations Desert Shield and Desert Storm.

It was clear to the military leaders planning this action that military personnel engaged in these actions would be exposed to a variety of risks. A number of preventive measures were taken for the purpose of protecting them from biological and chemical weapons; these measures included the administration of pyridostigmine bromide and special vaccinations. After months of tense military build-up in a stark and hostile desert environment, coalition military forces fought a successful air war, followed by a four-day ground war.

For some Gulf War military personnel, however, the trauma and pain of war did not end with the ceasefire. Veterans returned home, and began to come to VA for help with a variety of symptoms and illnesses. They reported a long list of environmental exposures which occurred during their service in the Gulf War. We listened to the veterans' concerns and utilized the increasing knowledge gained to design and implement special healthcare programs to serve their needs. These special Persian Gulf War programs are a supplement to the comprehensive healthcare services VA provides for the nation's veterans of other conflicts.

VA's Persian Gulf Registry health examination program was the first component of VA's comprehensive Gulf War response. VA developed the Registry in 1991, and implemented it in 1992. Persian Gulf War health programs in the days soon after the war were given high priority. Of note, the Persian Gulf Registry was not intended or designed to be a scientific research study. Neither was it designed to be a "stand-alone" healthcare program, nor to provide longitudinal follow-up to Gulf War veterans. It was never envisioned to be a mechanism to monitor health outcomes. Instead, the Registry was established primarily to assist Gulf War

veterans gain entry into the continuum of VA care and to act as a health screening database. As such, VA staff are instructed to encourage all Gulf War veterans, symptomatic or not, to get a Registry examination.

VA's Persian Gulf War Registry serves a valuable function, but it also has significant limitations, including providing information only on a self-selected population and being a single evaluation of veterans examined over a variable time period since their Gulf War service.

Since the Registry examination program was initiated, VHA's Gulf War programs have grown to encompass a comprehensive approach to health services, addressing relevant medical care, research, and educational issues. In 1993, at the request of VA, Congress passed legislation later enacted as Public Law 103-210, giving Persian Gulf War veterans special eligibility (priority care) for VA healthcare. This law gave VA the authority it requested to treat Gulf War veterans who have health problems which may have resulted from an environmental or hazardous exposure during Gulf War service. VA now provides Gulf War Registry health examinations and hospital and outpatient follow-up care at its medical facilities nationwide, specialized evaluations at four regional Referral Centers, and readjustment and sexual trauma counseling to Gulf War veterans. To date, more than 66,000 Gulf War veterans have completed Registry examinations; more than 1.8 million ambulatory care visits have been provided to 191,000 veterans; more than 19,000 veterans have been hospitalized at VA medical facilities; nearly 400 veterans have received specialized Referral Center evaluations; and more than 74,000 Gulf War veterans have been counseled at VA's Vet Centers.

REGISTRY EXAMINATIONS

Gulf War veterans participating in the Registry examination program have commonly reported that they suffer from a diverse array of symptoms, including fatigue, skin rash, headache, muscle and joint pain, memory problems, shortness of breath, sleep disturbances, gastrointestinal symptoms, and chest pain. These multisystem symptoms have been treated seriously, and veteran patients have received medical evaluations, as appropriate. Of note, 12 percent of the VA Registry examination participants have had no specific health complaints but, have wished to participate in the examination because they were concerned that their future health might be affected as a consequence of their service in the Persian Gulf War. Overall, while 26 percent of the Registry participants rated their health as poor, 73 percent receiving this examination reported their health as all right to good. To date, the diagnoses received by Registry participants do not cluster in one organ system or disease category. Instead, the diagnoses span a wide range of illnesses and diagnostic categories. This data has been provided to the Subcommittee on a number of occasions.

Only a minority of symptomatic Gulf War veterans who have been evaluated in the VA Registry have unexplained illnesses. Depending on the particular methodology used, between 10-25 percent of veterans from the Registry who have been examined have been found to have unexplained illnesses. While some symptoms of Gulf War veterans are difficult to diagnose and remain unexplained, there is consensus among government and non-government physicians and scientists alike that current evidence does not support the commonly held lay impression that these illnesses represent a single, unique illness that can explain every Gulf War veterans symptoms. As such, the

unexplained illnesses of Gulf War veterans do not meet the clinical definition of a medical syndrome, per se.

As previously stated, the majority of Gulf War veterans have a wide spectrum of diagnosed medical conditions. The overall frequency of unexplained symptoms among Gulf War veterans appears to be about the same as in a general medical practice (i.e., a non-VA or non-military general medical practice). I should stress, however, that this in no way diminishes the importance of these health problems or the intensity or type of evaluation the symptomatic person receives at VA facilities. Also, does this mean that care for Gulf War veterans with diagnosed or undiagnosed illnesses has been ignored by VA? The answer is absolutely no.

We recognize that the wide variety of medical conditions diagnosed in Gulf War veterans, and the lack of a unique Gulf War Syndrome per se has created a significant set of challenges for VA clinicians. We believe that Gulf War veterans who seek care from VA are suffering from genuine illnesses and, as indicated already, we are providing a substantial amount of healthcare and treatment for these veterans.

TREATING AND MANAGING PERSIAN GULF WAR VETERANS' ILLNESSES

This Subcommittee has asked that I address the Department's efforts to treat and manage the relatively small group of veterans having ill-defined health problems, as well as VA's evaluative findings regarding the treatments provided.

The difficulty VA has with monitoring and evaluating the results of treatment and precisely determining the outcomes of our healthcare efforts are directly related

to the lack of a single consistent, definable medical condition in Gulf War veterans. Approximately 75 percent of symptomatic Gulf War veterans in our Registry who have been examined have had their condition definitively diagnosed and treated. Treatments are based on the best contemporary medical knowledge and are tailored to the individual veteran's complaints and symptoms. There is no cookbook or formula approach to treatment that will give relief to every Gulf War veteran who is treated. We must rely on the clinical skills and best medical judgment of VA's physicians and other practitioners. VA clinicians must also carefully evaluate the latest and best available therapies for "symptom syndromes" such as chronic fatigue syndrome and fibromyalgia that are seen in a number of Gulf War veterans. We encourage the use of innovative and non-traditional forms of therapy, although specific treatments employed remain the prerogative of the treating clinician. We use both monitored clinical and research approaches to obtain the maximum information from our efforts. These ill-defined symptoms provide equal challenges to VA and non-government healthcare providers alike. Treatments provided by VA healthcare providers meet the high standards that we set for VA healthcare in general. The quality of care for veterans, including Gulf War veterans is subject to continuous external and internal peer-review and scrutiny.

Your questions do raise some significant issues that have been a source of frustration to VA healthcare providers and to me personally. We have heard testimony, listened to statements made in veterans forums, and heard from veterans one-on-one in our examination rooms around the nation. Some Gulf War veterans are dissatisfied with the availability of or access to VA care. Others complain about the continuity of their healthcare. Still others rate individual

clinicians highly, but are very frustrated that they have symptoms from an uncertain cause. We share these frustrations and have tried to restructure services to deal with these issues.

As you know, the Veterans Health Administration is undergoing a massive reorganization. We are in the process of transitioning from a predominantly inpatient system to an outpatient-based healthcare delivery system. We are implementing primary care teams nationwide for every veteran, including Gulf War veterans. It has been our judgment that primary care would be helpful in providing both better access to and continuity of healthcare. On the other hand, primary care teams have not always provided an acceptable solution for some veterans with complex medical problems. Many of these veterans, and certainly the most complex Gulf War cases, need a system of care which utilizes case management. This is one of the reasons that increased case management will be targeted in our VISN Director performance contracts. We believe that case managed care should be an integral part of VA's healthcare delivery system, if not the foundation of the system since VA treats so many patients with complex medical and socioeconomic conditions. As we move forward in these areas, we will keep the Committee informed of our progress.

While VA has been a leader in the development of veterans healthcare programs, improvement of understanding concerning PGW health issues and dissemination of knowledge on Gulf War-related health issues, and while we believe that our programs have been well designed, we also know that they are neither uniformly delivered nor perfect. We also recognize that some veterans have not received the kind of reception or care at VA medical facilities that we can be proud of. To both you and those veterans I pledge that the Veterans

Health Administration (VHA) is working diligently to improve their satisfaction with our services.

In this regard, VHA has established quality monitors and performance standards for the Registry program. In February, I established Service Evaluation and Action Teams (SEATs) within the Veterans Integrated Service Networks to evaluate and improve healthcare delivery and customer satisfaction. The SEATs are envisioned to first address Gulf War veterans and, if successful, later be used for other programs. VHA has also developed a new customer satisfaction survey which over-samples Gulf War veterans. This survey will, for the first time, provide us the opinions of Gulf War veterans. The survey will produce adequate statistical power from which to draw valid conclusions about these data. These programs will allow us to collect data for quality improvement of VA programs and support our goal of providing the highest quality care to veterans.

EDUCATION

In order to keep our healthcare providers well informed about the latest developments related to Gulf War veterans, VA has utilized a wide array of communication vehicles, including periodic nationwide conference calls, mailings, satellite video-teleconferences and annual on-site continuing medical education (CME) conferences. In 1995 and 1996, we broadcast teleconferences on undiagnosed illnesses and on the evaluation and management of chronic fatigue syndrome. A 1996 CME conference was comprised of workshops focused on evaluation and management of common symptoms and medical conditions identified in Gulf War veterans. The latest national Persian Gulf War CME

conference was held on June 3-4, 1997, in Long Beach, California; it was judged by participants as being highly informative and useful.

VA's past internal educational efforts have been primarily aimed at developing a dedicated cadre of well-informed Registry physicians and staff, who in turn provide a source of education and consultation to other healthcare providers at their facilities. However, with the advent of primary care and the growing recognition that the health problems of Gulf War veterans span all medical subspecialties, we believe VA needs to expand its educational programs. We see an opportunity to improve the understanding of Gulf War-related health issues by other medical personnel. Our goal is that all VA healthcare providers will have a working understanding of Gulf War exposures and health issues and will be able to discuss with their Gulf War patients how these issues could impact on their current or future health status. In order to meet this challenge and continue to improve our programs, the Veterans Health Administration has developed and will publish a self-study Persian Gulf CME program for every VA physician this year. We will make this available to non-VA physicians, at cost, as well. The Presidential Advisory Committee found that our Registry and Referral Center personnel were indeed knowledgeable and well-informed about all aspects of Persian Gulf War veterans' health issues. However, they opined that education of healthcare providers not directly involved in the Registry program and VA's risk communication efforts should be enhanced and augmented. VA agrees, and efforts to accomplish this are already underway.

RESEARCH

In order to get the best assessment of the health status of Gulf War veterans, a carefully designed and well executed research program is necessary. VA, as lead agent for federally- sponsored Persian Gulf War research programs, has laid the foundation for such a research plan. Under the auspices of the Persian Gulf Veterans Coordinating Board's Research Working Group, VA has developed a structured research portfolio to address the currently recognized, highest priority medical and scientific issues. More than 90 research projects are in progress and or have been completed. We continue to search for answers and to expand our understanding of the complex array of issues related to Gulf War veterans' illnesses.

VA's own research programs related to Gulf veterans' illnesses include more than 30 individual projects being carried out nationwide by VA and University-affiliated investigators.

After initiating a nationwide competition in 1993 VA established three Environmental Hazards Research Centers in 1994. All three Centers are carrying out projects which address aspects of the potential adverse health outcomes of exposure to a wide variety of hazards, including chemical warfare neurotoxins. In 1996, we established a fourth center at the Louisville VAMC for investigation of adverse reproductive outcomes. In addition, VA's Environmental Epidemiology Service has completed an initial Persian Gulf Veterans Mortality Study and has begun a long-term mortality study. The VA National Health Survey of Persian Gulf Veterans and Their Families is being carried out by the VA's Environmental Epidemiology Service. Phase I, a postal survey of 15,000 Gulf War veterans and a comparison group of 15,000 Gulf era veterans, was completed in August 1996. The questions on this survey asked veterans to

report health complaints, medical conditions, and possible exposures to a wide variety of possible environmental agents, including potential nerve gas or mustard gas exposure. Phase II will consist of 8,000 telephone interviews and a review of 4,000 medical records. Phase II will address the potential for non-response bias, provide a more stable estimate of prevalence rates for various health outcomes, and verify self-reported health outcomes in medical records. The Phase III examination protocol for the examinations of veterans and their family members is in final planning stages. Details of these and other government-sponsored research studies are included in the report Federally Sponsored Research on Persian Gulf Veterans Illnesses for 1995. Copies of this report and its update have been previously provided to the Subcommittee.

Lastly, you asked that I discuss current or planned VA research regarding health outcomes associated with particular approaches to treatment or management of the health problems of Gulf War veterans. Research on Gulf War health issues has proceeded according to an orderly and coordinated strategic plan. It has progressed from initial descriptions of individual veterans' health problems, to cluster investigations, to descriptive epidemiology studies and basic science investigations of the potential adverse health effects of specific exposures which occurred during Gulf War service. While these efforts represent a reasonable approach and a good beginning, I have asked VA's Research Service to take a completely fresh and comprehensive look at these issues in light of the growing realization of the complexity of the medical issues involved. This new effort will be fully coordinated with the Persian Gulf Veterans Coordinating Board.

Specifically, first I have asked them to develop a research strategy for studying the health effects of low-level exposure to chemical warfare nerve agents.

During March of this year, VA sponsored an international conference on the health effects of low-level exposure to chemical warfare nerve agents. The findings and conclusions of this conference will play a key role in the development of our research strategy. Low-level chemical exposure issues are of great importance to veterans of the Gulf War, as well as to the entire U.S. population. I also believe it is essential to bring together a multi-disciplinary interagency group of experts to focus on finding innovative solutions to these perplexing issues. Further, I agree that it is now appropriate for research to look at treatments for those conditions that occur in Gulf War veterans for which a case definition exists and which, therefore, lend themselves to prospective research studies (for example chronic fatigue syndrome and fibromyalgia), even though the occurrence of such conditions may not be widely supported by medical scientists. Finally, I have asked the Office of Research and Development to provide increased focus on outcomes research for Gulf War and other veterans.

A question that naturally arises is whether there are effective ways of treating undiagnosed, symptom-based illnesses which may not have measurable physiologic findings. In the traditional view of treatment outcomes research such undifferentiated, symptom-based illnesses are not amenable to outcomes research because one or all of the following requirements for a treatment trial are lacking: a clearly defined definition of the disease, a clearly defined health outcome, and a single treatment aimed at a biologically plausible etiology. Treatment trials are the foundation of evidence-based medicine, which is changing the way clinicians carry out their mission by informing them of the best, most effective approaches to treatment and care.

The VA Office of Research and Development has a long tradition of supporting outcomes research and devotes over \$40 million per year in this area. As an example of the type of studies it supports, VA has recently launched a new cooperative (multi-center) trial on treatment for PTSD. This study expands traditional pharmacological approaches to PTSD to include more complex non-pharmacological treatment approaches. The primary objective of this trial is to evaluate the efficacy of trauma-focused group therapy for treating PTSD symptoms. VA is also interested in additional ideas for treatment of patients with PTSD, and will shortly circulate a program announcement for additional VA cooperative studies. We will be specifically soliciting trials of non-pharmacological and innovative treatments of PTSD; trials for treatment of PTSD in special subpopulations such as women, Gulf War veterans, the Vietnam veterans, the so-called “atomic veterans” and others; studies of treatments aimed primarily at comorbid disorders prevalent among PTSD patients; and studies of the effects of treatments on “preclinical” markers that might be used as screens for treatment strategies which would then be subject to additional scientific testing. The findings of such research, along with the development of novel methodological approaches to outcomes research on non-pharmacological and non-conventional treatments of PTSD, should have multiplicative benefits for research and treatment for undiagnosed illnesses.

Research related to the illnesses of Gulf War veterans is highly complex, and this is equally true of outcomes research. VA is committed to meeting these challenges and providing quality healthcare and the most effective treatments to Gulf War veterans. We will continue to solicit the advice of scientific experts, oversight groups and this Sub-committee to improve our programs for veterans. VA healthcare providers are dedicated to providing compassionate care and

answering important medical questions. President Clinton has made it clear that no effort should be spared in this regard.

Although both the treatment and research for Persian Gulf veterans have been strong, we have proactively taken steps to improve the program when weaknesses have been identified. We believe the approaches being pioneered for these veterans will benefit others in the future. We welcome your specific suggestions for how VA care can be improved and how VA can be more responsive to those who it serves.

That concludes my statement. I will be happy to answer your questions.